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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,635	06/08/2001	James N. Herron	3278.2US	9774

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/877,635	HERRON ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2004 and 09 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 21-33 and 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21, lines 7-10, contains language that is confusing, and thus it is unclear what Applicant is claiming.

Fore example, claim 21, lines 7-10, recites the limitation "a light detector for detecting fluorescent light passed through.....and emitted as fluorescently labeled tracer molecules that indicate binding of...with a capture molecule are excited by the evanescent field,..." The claim appears to recite that the fluorescent light is emitted as tracer molecules; however, fluorescent tracer molecules are not part of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 21-33, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt, 4,849,340, in view of Jackowski, 5,747,274.

Oberhardt discloses the invention substantially as claimed. Oberhardt discloses an assay system comprising: a waveguide (27 and 10) configured to generate an evanescent field (col. 22, lines 27-31) over at least one planar surface having capture molecules (col. 22, lines 29-31);

a light source (120) positioned to direct light into said waveguide;

a light detector (121) for detecting fluorescent light passed through said planar surface and an opposite surface of said waveguide (col. 11, lines 41-44; and col. 22, lines 38-43, and light ray 40 in figure 29) and emitted as fluorescently labeled tracer molecule (col. 22, line 29), which indicate binding (col. 22, line 32), are excited by the evanescent field (col. 11, line 44 and col. 22, lines 27-31); said light detector generating an intensity signal indicating an intensity of said detected light (col. 11, line 12);

and a controller (i.e., processor 182, col. 18, line 16, and col. 19, line 34) for monitoring said intensity signal and being capable of correlating said intensity signal to a concentration of at least one indicator of coronary artery disease in the sample.

As to claim 22, said waveguide is optically associated with a rear lens (191) oriented for reading light from said light source passing through said waveguide, to monitor coupling efficiency and beam quality. (Although element 191 is described as a second external waveguide in column 22, line 42, it is considered a lens since it is a transparent material used in forming an image.)

As to claim 24, said at least one reaction area comprises a reservoir (containing reaction volume 66, col. 22, lines 28-29.)

As to claim 25, said at least one reaction area comprises a well (see fig. 29.)

As to claim 26, said controller (i.e., processor 182) is capable of correlating in a substantially continuous fashion.

As to claims 27 and 29, said controller (182) is capable of being configured to effect said monitoring and said correlating until a reliable determination is made of whether said at least one indicator of coronary artery disease is present in an amount indicative of coronary artery disease (col. 19, lines 33-41.).

As to claims 28 and 30, said controller (182) is capable of being configured to output a signal that effects reporting of said reliable determination (col. 19, lines 33-41.)

As to claim 31, said controller is capable of being configured to substantially simultaneously determine concentrations of a plurality of indicators of coronary artery disease (col. 19, lines 33-41.) (Examiner notes that Applicant is claiming a device, and thus the prior art meets the device since it is capable of performing the intended function.)

As to claim 45, the at least one planar surface (10) of the waveguide comprises optical plastic (col. 15, line 23.)

As to claim 46, the system further comprises a first member (30, see figure 29) associated in liquid tight attachment with said at least one planar surface of said waveguide, wherein said first member, in conjunction with said waveguide, defines at least one reaction area for containing the biological liquid sample while said at least one

planar surface of said waveguide defines a floor or ceiling of said at least one reaction area (see figure 29, and col. 22, lines 25-29.)

Oberhardt teaches that the system is used for assays utilizing immobilized molecules for binding to molecules in samples, the assay being analyzed with a fluorescence detector, (col. 22, lines 29-31; see also col. 29, lines 40-43, col. 30, lines 15-16.)

However, Oberhardt does not specifically disclose that the capture molecules on the planar surface is for capturing at least one indicator of coronary artery disease.

As to claim 23, Oberhardt does not disclose that the capture molecules include capture molecules that bind with at least a portion of at least one of a troponin, creatine kinase, or myoglobin molecule or complex.

As to claim 32, Oberhardt does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one ischemic marker or at least one complex that includes at least one ischemic marker.

As to claim 33, Oberhardt does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one marker released from cardiac tissue only after a myocardial infarction or at least one complex that includes marker released from cardiac tissue only after a myocardial infarction.

Jackowski likewise teaches an assay system comprising immobilized molecules, a waveguide, see column 27, line 47 – column 28, line 11, and column 29, lines 1-31, and fluorescence detector, see column 28, lines 12-38. In addition, Jackowski teaches use of capture molecules that bind with troponin, creatine kinase, or myoglobin, see

column 4, lines 35-36, and column 5, lines 29-31, for the detection of myocardial infarction, see column 4, lines 32- column 8, line 31, and column 19, lines 8-14, and column 29, lines 51-63, and column 29, lines 51-63, and column 22, lines 1-12, wherein the capture molecule is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27. Moreover, Jackowski teaches that the capture molecules can be used in various techniques available in optical sensor technology (see column 29, lines 28-31.)

It would have been obvious to utilize the capture molecules for the detection of myocardial infarction as taught by Jackowski, on the Oberhardt waveguide since Jackowski teaches that such capture molecules can utilize known optical sensor technology with the disclosed capture molecules in order to detect myocardial infarction, as would be desirable to prevent a medical problem. The Oberhardt waveguide is a known optical sensor technology, and given the teachings of Oberhartd and Jackowski, one of ordinary skill in the art would have reasonable expectation of success.

Response to Arguments

Applicant's arguments with respect to the Foster '277 reference used in the rejection in the previous Office action have been considered are moot in view of the new ground(s) of rejection as a result of the amendments to the claims.

The arguments with respect to Jackowski are not persuasive because they pertain to intended use, and the prior art device is capable of performing the intended use, as indicated above.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that as to claim 22, the Jackowski reference does not teach a waveguide which is optically associated with a rear lens oriented for reading light passing through the waveguide to monitor coupling efficiency and beam quality. Examiner reasserts that Oberhardt reference discloses light passing through a waveguide and rear lens oriented for reading light passing through the waveguide as described above.

As to claim 26, Applicant argues that Jackowski does not disclose a controller that is configured to effect correlation of at least one indicator of coronary artery disease in a liquid biological sample in a continuous fashion, but rather at a specific point in time. The Oberhardt reference discloses the claimed controller as described above. The controller in Oberhardt reference can be used in a continuous fashion.

As to claims 27 and 29, Applicant argues that Jackowski does not disclose a controller configured to effect monitoring and correlating until a reliable determination is made of whether at least one indicator is coronary artery disease is present in a liquid biological sample in an amount indicative of coronary arter diesase, but rather appears

to teach electronics that effect a single sweep of a surface of a waveguide and process the data obtained during that sweep. Examiner asserts that the controller in Oberhardt is capable of monitoring and correlating until a reliable determination is made of whether an indicator is present in an amount indicative of coonary artery disease.

As to claim 31, Applicant argues that Jackowski does not disclose a controller that is configured to substantially simultaneously determine concentrations of a plurality of indicators of coronary artery disease, but rather a single sample may be simultaneously run. Examiner notes that claim 31 does not require that the indicators be of different types of indicators. Thus, the Oberhardt controller is capable of substantially simultaneously determining concentrations of a plurality of indicators of coronary artery disease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

Christopher L. Chin

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9/30/04